

REMARKS

Claims 8-13, 16, 19, 20, 22-24, 26 and 71-93 are pending.

Claims 8, 91, and 93 have been amended to remove language that has not been considered by the Office. See pgs.4-5 of the instant Action.

Claims 1-7, 14-18, 21, 25, 27-70, and 84-86 have been cancelled without prejudice or disclaimer of any subject matter. The right to file a continuation as to cancelled subject matter is reserved.

New claims 94-120 are new and have been written along lines of the pending claims. To assist the Examiner in her review of the new claims, Applicants provide the following claim support table:

New Claim Support Table

New Claim	Support in pending claim:	New Claim	Support in pending claim:
94	10	108	76
95	11	109	77
96	12	110	78
97	13	111	79
98	19	112	80
99	20	113	81
100	22	114	82
101	23	115	83
102	24	116	87
103	26	117	88
104	72	118	89
105	73	119	90
106	74	120	9
107	75		

Additional support for new claims 94-120 can be found, for instance, in the specification and Drawings as filed originally as well as in previous responses, particularly the response filed on September 30, 2008.

In particular, new claims 94-120 are dependent on pending claims 91 or 93 which claims feature an apparatus in which at least one of the heat sources includes a heating unit and a cooling unit (a liquid or fan that removes heat, for instance).

No new matter has been added by virtue of the new claims or amendment of any pending claim.

Priority Under 35 USC §119

Applicants gratefully acknowledge the Office statements on pg. 2 of the Action, paragraph 2, that claims 8-13, 19, 20, 22, 23, 24, 26, 71-83, 87, 88-91, 92, and 93 are entitled to a priority date of September 15, 2001.

According to the Office, claims 16, and 84-86 find support in the CIP filed on March 15, 2004. While Applicants agree with this position, the claims are presently canceled to simplify the claim set. Applicants reserve the right to file a continuation as to these claims.

New claims 94-120 have been written along lines of pending claims entitled to the September 15, 2001 priority date. Accordingly, Applicants submit that each of the new claims is also entitled to that date.

Double Patenting Rejection

In the Office Action dated April 1, 2008, claims 8, 16 and 20 were provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 7 and 8 of co-pending application no. 10/836,376 (now U.S. Patent No. 7,488,595). Claim 16 has been cancelled by this paper. As the rejection of the remaining claims 8 and 20 was provisional, Applicants will address the rejection once one or more claims of the instant application are in condition for allowance.

Claim Rejections Under 35 USC § 103

Applicants gratefully acknowledge that the prior response and Rule 131 Declaration were deemed sufficient to overcome Benett et al. WO 02/072267 as a reference. Applicants further acknowledge withdrawal of several prior obviousness rejections based on the PCT reference. See pgs. 3-4 of the instant Office Action.

On pg. 6 of the Office Action, paragraph 15, the Office took the position that claims 8-12, 19-20, 22-23 and 26 stand rejected over Hunicke-Smith (WO 97/48818) in view of Malmquist (USP 6,783,993 published as WO00/58013 on October 5, 2000) and in further view of Haff et al. (USP 5,720,923). Applicants respectfully traverse the rejection on grounds that they conceived and reduced the claimed invention to practice well before the Malmquist PCT application publication date of October 5, 2000. In particular, the attached Second Rule 131 Declaration provides evidence that the inventors conceived and reduced the claimed invention to practice well before that date. Accordingly, withdrawal of the Malmquist US Patent No. 6,783,993 (and WO00/58013) as a reference is respectfully requested.

Second Declaration Under 37 CFR 1.131

Turning to the Second Rule 131 Declaration attached to this paper, the inventors state that they conceived and reduced the claimed invention to practice in the Republic of Korea («Korea») well before October 5, 2000. Decl. at ¶3. Korea became a WTO member country after January 1, 1996 and thus inventive activities occurring after that date, as set forth in the Declaration for instance, can be used as a basis for establishing prior conception and reduction to practice of the claimed invention. 37 CFR 1.131, MPEP §§ 715 and 201.13.

In particular, it is stated at ¶4 of the Declaration that well before October 5, 2000 there was recognition by at least one inventor of the need to make (or have made under their direction and supervision) a nucleic acid sequence amplification apparatus as described in the instant (subject) application that uses convection-based PCR (hereinafter «apparatus»). That conception included recognition of a need to make the apparatus with a plurality of heat sources which supply heat to or remove heat from a plurality of specific regions in a sample. See pending claims 8, 91 and 93 for instance.

It is further stated at ¶¶ 5-6 of the Declaration, that at least one inventor saw the need to make the apparatus well before October 5, 2000 in which the plurality of heat sources are arranged such that a first heat source that provides heat to a lower portion of the sample is located lower in height than a second heat source that removes heat from an upper portion of the sample. Further stated is recognition of need to configure the first heat source to create a spatial temperature distribution with spatial regions fulfilling temperature conditions suitable for convection PCR in the apparatus. See pending claims 8, 91 and 93 for instance.

As stated ¶7 of the Declaration, the apparatus included a first and second heat source and an insulator positioned between the first and second heat sources. See pending claims 8, 23, and 91, for instance. See also Appendices 1 and 2 of the Declaration.

It is stated at ¶¶8-9 of the Declaration that the apparatus was designed well before October 5, 2000 to have copper inlet and outlet tubes to accomodate a liquid (water) for thermal contact with a specific region of the sample in contact with the second heat source. As further stated, the second heat source was further designed well before October 5, 2000 to include a receptor in which the liquid was contained to remove heat from the sample. A further stated at ¶9 of the Declaration, the inlet and outlet tubes and the receptor of the second heat source were made to produce or assist a circulation unit that would circulate liquid through the apparatus. See pending claims 9, 10, 11, 71 and 72 for example.

It is further stated at ¶10 of the Declaration that well before October 5, 2000 the apparatus was made to include a plurality of heat sources with a first thermally conductive solid in thermal contact with a lower portion of the sample and a second thermally conductive solid in thermal contact with an upper portion of the sample. As stated, copper was used to facilitate the heat transfer in the solids. See pending claim 19, for instance.

It is further stated at ¶11 of the Declaration that well before October 5, 2000 at least one of the inventors conceived and made the apparatus in which at least one of the heat sources included a thermally conductive solid in thermal contact with a specific region of the sample. See claim 9.

It is further stated at ¶12 of the Declaration that well before October 5, 2000, the apparatus was made to include an opening defined by the first and second heat sources and the insulator. See pending claim 73, for instance.

Particular opening configurations in the second heat source were made well before October 5, 2000 as stated at ¶13 of the Declaration. These included an opening for receiving the reaction vessels that included a first through hole within the second heat source, a second through hole within the insulator and an opening within the first heat source. See pending claims 75-78. As stated, the opening was essentially perpendicular to the insulator and was adapted to receive the reaction vessel configured as a straight cylinder or tube. As stated at ¶14 of the Declaration, the apparatus was made to have certain sample through holes with a closed bottom end within the first heat source. See pending claims 74 and 92, for example.

As stated at ¶¶15-17 of the Declaration, at least one of the inventors identified and used reaction parameters to test the apparatus under convection PCR conditions established well before October 5, 2000. In particular, the inventor had successfully demonstrated that the apparatus worked to amplify a nucleic acid sequence using convection PCR well before October 5, 2000. See ¶17 of the Declaration.

As stated at ¶¶18-20 of the Declaration, at least one of the inventors had concluded from data provided in Appendix 5, for instance, that the apparatus made and tested well before October 5, 2000 could produce a spatial temperature distribution with spatial regions fulfilling temperature conditions suitable for (i) a denaturation, (ii) an annealing step in which the single strand DNAs formed in the denaturation step hybridize to the primers to form DNA-primer complexes, and (iii) a polymerization step in which the primers in the DNA-primer complexes are extended by the polymerization reaction. See claims 8, 91 and 93 for instance.

At least one of the inventors further concluded from data show in Appendix 5, for instance, that the heat sources of the apparatus were arranged to provide for a spatial temperature distribution with a convection region position between a relatively high temperature region (from the first heat source) and a relatively low temperature region (from the second heat source). See Decl. at ¶21 and pending claim 26, for instance.

As further stated at ¶¶22-25 of the Declaration, at least one of the inventors had conceived of and reduced to practice various reaction vessel configurations for use with the apparatus well before October 5, 2000. See pending claims 79-81, 83, and 87-88.

As also stated in the Declaration at ¶23, the inventors concluded from information that a reaction vessel with a single passage used in our apparatus achieved nucleic acid amplification through bidirectional convection (i.e., both upward and downward convection) within the reaction vessel. See claim 22.

It is also stated in ¶26 of the Declaration that well before October 5, 2000 at least one of the inventors conceived of the need to introduce a vertical gap between the top of the relatively high temperature region and the bottom of the relatively low temperature region. As further stated, a gap could be introduced between the sample and at least the second heat source. See claims 23, 89 and 90.

Further stated in ¶27 of the Declaration, is that well before October 5, 2000 at least one of the inventors conceived of the need and made the apparatus to include an air insulator. See claim 24.

The apparatus cited in the Second Rule 131 Declaration is disclosed throughout the subject application including the Drawings and claims as filed originally. For example, see Figs. 1, 3a, 3b (disclosing, for example, an example of the claimed invention and a reaction tube showing convection PCR). See also supporting disclosure under the Brief Description of the Drawings and under the «Best Mode For Carrying out the Invention» section of the instant application. See also the Examples section (providing particular reaction vessel configurations and conditions for performing convection PCR with the apparatus). Further support can be found in the prior responses filed in this case.

In view thereof, Applicants submit that they have provided sufficient evidence to show that the claimed invention was conceived and reduced to practice well before October 5, 2000. Since the present application claims priority to a date or dates less than one year after October 5,

2000, removal of USP 6,783,993 to Malquist (and WO00/58013) as a prior art reference is requested.

As relied on, none of the other references of record, taken individually or together, are sufficient to substantiate the instant obviousness rejection. Reconsideration and withdrawal of the rejection are therefore requested.

Remaining Rejections Under 35 USC § 103

Each of the remaining obviousness rejections set forth on pgs. 7-29 in the present office action rely on the WO00/58013 to Malquist as cited by the Office. Applicants respectfully submit that they have successfully antedated the Malmquist US Pat. No. 6,783,993 and corresponding PCT WO00/58013 as prior art references under 37 CFR 1.131. Accordingly, reconsideration and withdrawal of the remaining rejections are requested.

As relied on, none of the other references of record, taken individually or together, are enough to substantiate the obviousness rejections set forth on pgs. 7-29 of the instant Office Action. Reconsideration and withdrawal of the rejection are therefore requested.

Conclusion

Applicants believe that no further fee is due to consider the present amendment. Nevertheless, the Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. **502486**.

Dated: June 1, 2009

Respectfully submitted,

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